TRADE SECRET

Study Title

[redacted] **TWO YEAR ORAL TOXICITY-ONCOGENICITY STUDY IN RATS PEER REVIEW OF OVARIES**

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[redacted] Two Year Oral Toxicity-Oncogenicity Study in Rats
Peer Review of Ovaries

The slides from the ovaries from [redacted] Two Year Oral Toxicity-Oncogenicity Study in Rats were peer reviewed by two veterinary pathologists: Peter C. Mann, DVM, Diplomate, American College of Veterinary Pathologists and Steven R. Frame, D.V.M., Ph.D, Diplomate, American College of Veterinary Pathologists. The slides were originally examined and reported by Dr. Robert Geil (study pathologist) for Riker Laboratories, Inc., 3M (Project Number: 0281CR0012). The peer review focused on proliferative lesions of the ovary. The peer review pathologists discussed issues related to diagnostic nomenclature and criteria and reached agreement on lesion diagnoses and grading, as well as interpretation of the peer review findings. This agreement is reflected in the following report.

Materials and Methods

All slides listed as available by the study pathologist were made available for the peer review. The ovaries from a few animals were not present at the time of the initial evaluation, and these same ovaries were not available for peer review. The original diagnoses and the peer review diagnoses for the ovaries for each animal are given in Appendix A. In those cases where the peer review pathologist agreed with the study pathologist, the peer review diagnosis is listed as "Agree". For the purposes of analysis, the data are separated into those animals that died on or before 53 weeks on study, and those animals that died after 53 weeks on study. The animals that died on or before 53 weeks on study included those sacrificed at the interim sacrifice and early deaths. Since none of these animals had any proliferative lesions in the ovaries in either the initial or peer review evaluations, they were not included in the reporting or analysis of data below.

Criteria for Diagnosis of Proliferative Changes in the Ovary

In the normal aging ovary of rats, senescent corpora lutea develop into interstitial glands. This gonadal stromal change presents as small glands, lined by cuboidal cells. In some cases, these cells may become more columnar and have a sertoliform appearance. In addition, luteal cells may appear in the ovarian stroma. These (luteal) cells may also appear to form glands, but they have a characteristic fine granular, foamy appearance which is not present in interstitial glands, although the latter cells may have a macrovesicular vacuolar cytoplasm. The above changes are normal for aging rats, and should not be diagnosed as proliferative changes.

Proliferative lesions (hyperplasia or neoplasia) intrinsic to the ovary are generally classified as either epithelial, gonadal stromal (sex cord-stromal) or germ cell in origin (Dixon et al, 1999; Peluso and Gordon, 1992; Alison et al., 1990). Proliferative lesions observed in the ovaries from the current study were all gonadal stromal in origin. This category includes lesions composed of granulosa, thecal, luteal or sertoli-like cells, or

mixed populations of these cell types (Dixon et al, 1999; Peluso and Gordon, 1992). It has been recommended that for the purposes of analysis and evaluation of carcinogenic risk, tumors derived from gonadal stromal cells be combined (Peluso and Gordon, 1992). Thus, for this peer review, hyperplasia and neoplasia were diagnosed as gonadal stromal hyperplasia and gonadal stromal adenoma, respectively (Peluso and Gordon, 1992).

Gonadal stromal hyperplasia is present when the interstitial and/or sertoliform cells (but not the normal luteal cells) form discrete or diffuse areas containing enlarged clusters or tubular profiles of stromal cells with or without an increase in fibrous connective tissue. Hyperplasia was graded from 1-4, depending on the relative size of the proliferation (increasing grade with increasing size).

Typically, there are no clear cytological features that distinguish gonadal stromal hyperplasia from gonadal stromal adenoma. Therefore, to allow for some consistency in diagnosis, the criteria established for gonadal stromal adenoma is based primarily on the somewhat arbitrary feature of two-dimensional size. Gonadal stromal adenomas are diagnosed if the diameter of the lesions is greater than 3mm (Dixon et al, 1999). This corresponds to about a single field using the 10x microscope objective. If an animal had both adenoma and hyperplasia present, only the adenoma was recorded. Since size is the primary criterion differentiating hyperplasia from tumor, the assessment of incidence data for these lesions included an evaluation based on the total incidence of proliferative gonadal stromal lesions (combined hyperplasia and adenoma).

Many of the ovaries diagnosed with gonadal stromal hyperplasia during the peer review of this study contained very small areas of proliferation which would probably not be diagnosed during a routine evaluation (Dixon et al, 1999; Peluso and Gordon, 1992). However, to ensure that no subtle dose-effect was overlooked, all possible proliferative changes were diagnosed during the review.

Incidences of proliferative lesions (gonadal stromal hyperplasia, adenoma, or hyperplasia/adenoma combined) were evaluated by the Cochran-Armitage trend test and the Fisher's exact test. Statistical significance was judged at $P \leq 0.05$.

Results

The presence of all proliferative lesions in the ovaries of individual rats is presented in Appendix A. The incidence of gonadal stromal hyperplasia and/or adenoma in the ovaries of all rats on study beyond the one-year (53-week) interim sacrifice is shown in Text Table 1. Rats sacrificed at the one-year interim sacrifice, as well as rats that died prior to the interim sacrifice, were not considered "at risk" for tumor development. This is reflected in the fact that the number of animals/group, as given is Table 1, is less than 50 (as appears in the original report) and varies slightly among groups based on the number of deaths in each group that occurred before the interim sacrifice. The number of animals examined per group also reflects animals for which no ovary was available for review. Incidences of ovarian lesions based on the original microscopic evaluation can be found in the original study report (Sibinski, 1987)

Table 1
Incidence of Gonadal Stromal Hyperplasia and Adenoma in Rats[a]

Dose	0	30	300
No. Examined	45	47	46
Hyperplasia (Total No.)	8	16	15
- Grade 1	6	7	5
- Grade 2	2	3	1
- Grade 3	0	5	6
- Grade 4	0	1	3
Adenoma	4	0	2
Adenoma and/or Hyperplasia	12	16	17

[a]Animals on study beyond the interim (53-week) sacrifice

There were no statistically significant increases in hyperplasia (total number), adenomas, or hyperplasia/adenoma combined in treated groups compared to controls. Some evidence of increased lesion grade for proliferative lesions was observed in the 300 ppm group. For example, incidences of proliferative lesions diagnosed with a grade of 3 or more (that is, grade 3, 4, or adenoma) was 4/45, 6/47 and 11/46 in the 0, 30, and 300 ppm groups, respectively. The incidences of lesions of grade 3 and above were statistical significant at 300 ppm (P = 0.046 and 0.048 for the Cochran Armitage and Fisher's test, respectively). However, treatment-related progression of proliferative lesions to the size criteria established for adenoma did not occur, as incidences of adenoma were highest in controls.

Discussion and Conclusions

The slides of ovaries of rats from a two-year feeding study with [redacted] were peer reviewed with emphasis on proliferative lesions of the ovary. Lesions diagnosed by the peer review pathologists as gonadal stromal hyperplasia or gonadal stromal adenoma corresponded to the diagnoses of tubular hyperplasia or tubular adenoma by the study pathologist (one granulosa cell tumor–a type of gonadal stromal tumor–was also diagnosed by the study pathologist). The diagnostic terms used by the peer review pathologists were based on more recently published nomenclature, and the more generic designation of gonadal stromal lesions better reflected the spectrum of morphologic changes observed in the proliferative lesions. Furthermore, based on current diagnostic nomenclature, tubular hyperplasia or adenoma would suggest an origin from ovarian surface epithelium rather than from ovarian stromal cells.

Except for differences in diagnostic nomenclature, results of the peer review were similar to those of the original study for the 300 ppm group. More disparate results occurred for the control and 30 ppm groups where more hyperplastic lesions (irrespective of the

nomenclature used) were observed by the peer review pathologists. Based on the results of the peer review, there were no statistically significant increases in gonadal stromal hyperplasia, adenoma, or adenoma and hyperplasia combined in treated groups relative to controls. Some evidence of increased lesion grade, which would correspond to an increase in size of stromal lesions, was observed in the 300 ppm group. However, adenomas occurred in greater incidences in the control group than in either of the treated groups.

References

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Appendix A:
Individual Animal Peer Review Results

0 ppm (Group 1)

ANIMAL #	WKS ON TEST	ORIGINAL DX	PEER REVIEW DX
IR-4576	25	WITHIN NORMAL LIMITS	AGREE
IR-4607	40	MALIGNANT LYMPHOMA, LYMPHOCYTIC	AGREE
IR-4580	52	WITHIN NORMAL LIMITS	AGREE
IR-4578	53	WITHIN NORMAL LIMITS	AGREE
IR-4582	53	WITHIN NORMAL LIMITS	AGREE
IR-4585	53	WITHIN NORMAL LIMITS	AGREE
IR-4588	53	WITHIN NORMAL LIMITS	AGREE
IR-4589	53	WITHIN NORMAL LIMITS	AGREE
IR-4590	53	WITHIN NORMAL LIMITS	AGREE
IR-4601	53	WITHIN NORMAL LIMITS	AGREE
IR-4608	53	WITHIN NORMAL LIMITS	AGREE
IR-4610	53	WITHIN NORMAL LIMITS	AGREE
IR-4620	53	WITHIN NORMAL LIMITS	AGREE
IR-4629	53	WITHIN NORMAL LIMITS	AGREE
IR-4630	53	WITHIN NORMAL LIMITS	AGREE
IR-4631	53	WITHIN NORMAL LIMITS	AGREE
IR-4632	53	CYST, UNILATERAL	AGREE
IR-4640	53	WITHIN NORMAL LIMITS	AGREE
IR-4577	99	WITHIN NORMAL LIMITS	AGREE
IR-4579	84	WITHIN NORMAL LIMITS	AGREE
IR-4581	85	WITHIN NORMAL LIMITS	AGREE
IR-4583	105	TUBULAR ADENOMA, UNILATERAL	GONADAL STROMAL ADENOMA, UNILATERAL
IR-4584	105	WITHIN NORMAL LIMITS	AGREE
IR-4586	105	NOT EXAMINED, MISSING	AGREE
IR-4587	105	WITHIN NORMAL LIMITS	AGREE
IR-4591	105	WITHIN NORMAL LIMITS	AGREE
IR-4592	88	WITHIN NORMAL LIMITS	AGREE
IR-4593	105	WITHIN NORMAL LIMITS	AGREE
IR-4594	79	WITHIN NORMAL LIMITS, ONE OF PAIR MISSING	AGREE
IR-4595	105	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4596	78	WITHIN NORMAL LIMITS	AGREE
IR-4597	105	TUBULAR ADENOMA, UNILATERAL	GONADAL STROMAL ADENOMA, UNILATERAL
IR-4598	105	TUBULAR ADENOMA	GONADAL STROMAL ADENOMA, UNILATERAL
IR-4599	102	MALIGNANT LYMPHOMA, HISTIOCYTIC	AGREE
IR-4600	99	CYST, UNILATERAL	AGREE

0 ppm (Group 1) – continued

ANIMAL #	WKS ON TEST	ORIGINAL DX	PEER REVIEW DX
IR-4602	105	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4603	105	WITHIN NORMAL LIMITS	AGREE
IR-4604	105	CYST, UNILATERAL	AGREE
IR-4605	77	CYST, UNILATERAL	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4606	105	NOT EXAMINED, MISSING	AGREE
IR4609	105	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4611	105	WITHIN NORMAL LIMITS	AGREE
IR-4612	105	WITHIN NORMAL LIMITS	AGREE
IR-4613	89	WITHIN NORMAL LIMITS	AGREE
IR-4614	105	WITHIN NORMAL LIMITS	AGREE
IR-4615	105	WITHIN NORMAL LIMITS	AGREE
IR-4616	105	CYST, UNILATERAL	AGREE
IR-4617	73	LEIOMYOMA	NOT PRESENT ON SLIDE, ONE OV IS WITHIN NORMAL LIMITS
IR-4618	93	WITHIN NORMAL LIMITS	AGREE
IR-4619	64	WITHIN NORMAL LIMITS	AGREE
IR-4621	99	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MILD, BILATERAL
IR-4622	62	WITHIN NORMAL LIMITS	AGREE
IR-4623	96	WITHIN NORMAL LIMITS	AGREE
IR-4624	100	CYST, UNILATERAL	GONADAL STROMAL HYPERPLASIA, MILD, UNILATERAL
IR-4625	100	WITHIN NORMAL LIMITS	AGREE
IR-4626	105	WITHIN NORMAL LIMITS	AGREE
IR-4627	105	TUBULAR ADENOMA, UNILATERAL CYST BILATERAL	GONADAL STROMAL ADENOMA, UNILATERAL; CYST BILATERAL
IR-4628	105	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4633	83	WITHIN NORMAL LIMITS	AGREE
IR-4634	105	WITHIN NORMAL LIMITS	AGREE

0 ppm (Group 1) - continued

ANIMAL #	WKS ON TEST	ORIGINAL DX	PEER REVIEW DX
IR-4635	94	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4636	105	WITHIN NORMAL LIMITS	AGREE
IR-4637	82	WITHIN NORMAL LIMITS	AGREE
IR-4638	105	WITHIN NORMAL LIMITS	AGREE
IR-4639	56	WITHIN NORMAL LIMITS	AGREE

30 ppm (Group 6)

ANIMAL #	WKS ON TEST	ORIGINAL DX	PEER REVIEW DX
IR-4751	42	WITHIN NORMAL LIMITS	AGREE
IR-4744	48	WITHIN NORMAL LIMITS	AGREE
IR-4735	50	WITHIN NORMAL LIMITS	AGREE
IR-4706	72	WITHIN NORMAL LIMITS	AGREE
IR-4707	90	WITHIN NORMAL LIMITS-ONE OF PAIR PRESENT	GONADAL STROMAL HYPERPLASIA, MILD, UNILATERAL
IR-4708	105	WITHIN NORMAL LIMITS	AGREE
IR-4709	99	WITHIN NORMAL LIMITS	AGREE
IR-4710	105	CYST	AGREE
IR-4711	105	WITHIN NORMAL LIMITS	AGREE
IR-4712	94	CYST	AGREE
IR-4713	97	WITHIN NORMAL LIMITS	AGREE
IR-4714	105	WITHIN NORMAL LIMITS	AGREE
IR-4715	105	CYST, UNILATERAL	AGREE
IR-4716	105	CYST, UNILATERAL	AGREE
IR-4717	105	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4718	94	WITHIN NORMAL LIMITS	AGREE
IR-4719	98	CYST, UNILATERAL	AGREE
IR-4720	105	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4721	95	WITHIN NORMAL LIMITS-ONE OF PAIR PRESENT	AGREE
IR-4722	83	WITHIN NORMAL LIMITS	AGREE
IR-4723	105	TUBULAR HYPERPLASIA, MODERATE	GONADAL STROMAL HYPERPLASIA, MODERATE, UNILATERAL
IR-4724	105	TUBULAR HYPERPLASIA, BILATERAL, MILD	GONADAL STROMAL HYPERPLASIA, MODERATE, BILATERAL
IR-4725	94	WITHIN NORMAL LIMITS	AGREE
IR-4726	105	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4727	105	CYST	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4728	84	WITHIN NORMAL LIMITS	AGREE

30 ppm (Group 6) - continued

ANIMAL #	WKS ON TEST	ORIGINAL DX	PEER REVIEW DX
IR-4729	105	WITHIN NORMAL LIMITS	AGREE
IR-4730	74	WITHIN NORMAL LIMITS	AGREE
IR-4731	99	MALIGNANT LYMPHOMA, HISTIOCYTIC	LYMPHOMA
IR-4732	99	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4733	105	WITHIN NORMAL LIMITS	AGREE
IR-4734	95	WITHIN NORMAL LIMITS	AGREE
IR-4736	105	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MILD, UNILATERAL
IR-4737	105	TUBULAR HYPERPLASIA, BILATERAL, MODERATE	GONADAL STROMAL HYPERPLASIA, MODERATE, BILATERAL
IR-4738	101	WITHIN NORMAL LIMITS	AGREE
IR-4739	105	WITHIN NORMAL LIMITS	AGREE
IR-4740	105	WITHIN NORMAL LIMITS	AGREE
IR-4741	97	WITHIN NORMAL LIMITS	AGREE
IR-4742	83	WITHIN NORMAL LIMITS	AGREE
IR-4743	97	WITHIN NORMAL LIMITS	AGREE
IR-4745	105	TUBULAR HYPERPLASIA, UNILATERAL, MODERATE GRANULOSA CELL TUMOR, BENIGN, UNILATERAL	GONADAL STROMAL HYPERPLASIA, MODERATE, UNILATERAL
IR-4746	87	WITHIN NORMAL LIMITS	AGREE
IR-4747	105	CYST, UNILATERAL	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL; CYST
IR-4748	81	WITHIN NORMAL LIMITS	AGREE
IR-4749	82	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4750	97	WITHIN NORMAL LIMITS	AGREE
IR-4752	105	CYST, BILATERALTUBULAR HYPERPLASIA, BILATERAL, MODERATE	GONADAL STROMAL HYPERPLASIA, SEVERE, BILATERAL
IR-4753	105	TUBULAR HYPERPLASIA, BILATERAL, MODERATE	GONADAL STROMAL HYPERPLASIA, MODERATE, UNILATERAL
IR-4754	105	CYST, UNILATERAL	AGREE
IR-4755	105	TUBULAR HYPERPLASIA, BILATERAL, MODERATE	GONADAL STROMAL HYPERPLASIA, MILD, BILATERAL

300 ppm (Group 5)

ANIMAL #	WKS ON TEST	ORIGINAL DX	PEER REVIEW DX
IR-4678	49	WITHIN NORMAL LIMITS	AGREE
IR-4642	53	WITHIN NORMAL LIMITS	AGREE
IR-4652	53	WITHIN NORMAL LIMITS	AGREE
IR-4655	53	WITHIN NORMAL LIMITS	AGREE
IR-4656	53	WITHIN NORMAL LIMITS	AGREE
IR-4664	53	WITHIN NORMAL LIMITS	AGREE
IR-4666	53	WITHIN NORMAL LIMITS	AGREE
IR-4669	53	WITHIN NORMAL LIMITS	AGREE
IR-4671	53	WITHIN NORMAL LIMITS	AGREE
IR-4674	53	WITHIN NORMAL LIMITS	AGREE
IR-4676	53	WITHIN NORMAL LIMITS	AGREE
IR-4687	53	WITHIN NORMAL LIMITS	AGREE
IR-4689	53	WITHIN NORMAL LIMITS	AGREE
IR-4692	53	WITHIN NORMAL LIMITS	AGREE
IR-4699	53	WITHIN NORMAL LIMITS	AGREE
IR-4704	53	WITHIN NORMAL LIMITS	AGREE
IR-4641	73	NOT EXAMNED, MISSING	AGREE
IR-4643	78	WITHIN NORMAL LIMITS	AGREE
IR-4644	105	WITHIN NORMAL LIMITS	AGREE
IR-4645	105	WITHIN NORMAL LIMITS	AGREE
IR-4646	105	TUBULAR HYPERPLASIA, MODERATE	GONADAL STROMAL HYPERPLASIA, MODERATE, UNILATERAL
IR-4647	105	CYST, UNILATERAL	AGREE
IR-4648	88	WITHIN NORMAL LIMITS	AGREE
IR-4649	105	TUBULAR HYPERPLASIA, BILATERAL, MODERATE	GONADAL STROMAL HYPERPLASIA, SEVERE, BILATERAL
IR-4650	104	TUBULAR HYPERPLASIA, BILATERAL, MODERATE	GONADAL STROMAL HYPERPLASIA, SEVERE, BILATERAL
IR-4651	96	NO DIAGNOSIS, INADEQUATE SECTION	AGREE
IR-4653	87	WITHIN NORMAL LIMITS	AGREE
IR-4654	57	WITHIN NORMAL LIMITS	AGREE
IR-4657	105	WITHIN NORMAL LIMITS	AGREE
IR-4658	105	CYST, UNILATERAL	AGREE
IR-4659	105	WITHIN NORMAL LIMITS	AGREE
IR-4660	105	WITHIN NORMAL LIMITS	AGREE
IR-4661	105	WITHIN NORMAL LIMITS	AGREE
IR-4662	105	WITHIN NORMAL LIMITS	AGREE
IR-4663	105	WITHIN NORMAL LIMITS	AGREE

300 ppm (Group 5) - continued

ANIMAL #	WKS ON TEST	ORIGINAL DX	PEER REVIEW DX
IR-4665	94	TUBULAR HYPERPLASIA, MODERATE	GONADAL STROMAL HYPERPLASIA, MODERATE, BILATERAL
IR-4667	105	TUBULAR HYPERPLASIA, MILD	GONADAL STROMAL HYPERPLASIA, MINIMAL, BILATERAL
IR-4668	81	WITHIN NORMAL LIMITS	AGREE
IR-4670	92	WITHIN NORMAL LIMITS	AGREE
IR-4672	105	TUBULAR HYPERPLASIA, UNILATERAL, MODERATE	GONADAL STROMAL HYPERPLASIA, MODERATE, BILATERAL
IR-4673	79	WITHIN NORMAL LIMITS	AGREE
IR-4675	105	WITHIN NORMAL LIMITS	AGREE
IR-4677	105	TUBULAR ADENOMA, UNILATERAL	GONADAL STROMAL ADENOMA, UNILATERAL
IR-4679	105	TUBULAR HYPERPLASIA, BILATERAL, MILD	GONADAL STROMAL HYPERPLASIA, MODERATE, BILATERAL
IR-4680	104	TUBULAR HYPERPLASIA, MODERATE	GONADAL STROMAL HYPERPLASIA, MINIMAL, BILATERAL
IR-4681	97	TUBULAR HYPERPLASIA, MODERATE	GONADAL STROMAL HYPERPLASIA, MODERATE, UNILATERAL
IR-4682	94	NOT EXAMINED, MISSING	AGREE
IR-4683	105	TUBULAR HYPERPLASIA, BILATERAL, MODERATE	GONADAL STROMAL HYPERPLASIA, MODERATE, BILATERAL
IR-4684	103	TUBULAR HYPERPLASIA, MODERATE	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4685	75	WITHIN NORMAL LIMITS	AGREE
IR-4686	105	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL

300 ppm (Group 5) - continued

ANIMAL #	WKS ON TEST	ORIGINAL DX	PEER REVIEW DX
IR-4688	105	TUBULAR HYPERPLASIA, MODERATE	GONADAL STROMAL HYPERPLASIA, SEVERE, UNILATERAL
IR-4690	105	WITHIN NORMAL LIMITS	AGREE
IR-4691	100	WITHIN NORMAL LIMITS	AGREE
IR-4693	105	WITHIN NORMAL LIMITS	AGREE
IR-4694	105	CYST, UNILATERAL	AGREE
IR-4695	105	WITHIN NORMAL LIMITS	GONADAL STROMAL HYPERPLASIA, MINIMAL, UNILATERAL
IR-4696	105	CYST, UNILATERAL	AGREE
IR-4697	105	WITHIN NORMAL LIMITS	AGREE
IR-4698	105	CYST, UNILATERAL	GONADAL STROMAL HYPERPLASIA, MILD, BILATERAL
IR-4700	96	TUBULAR HYPERPLASIA, MARKED	GONADAL STROMAL ADENOMA, UNILATERAL
IR-4701	105	WITHIN NORMAL LIMITS	AGREE
IR-4702	87	TUBULAR HYPERPLASIA, MODERATE	AGREE
IR-4703	105	WITHIN NORMAL LIMITS	AGREE
IR-4705	62	WITHIN NORMAL LIMITS	AGREE